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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/848,439	05/08/97	LAVALLIE	E	GI5288A

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EXAMINER	
UNGAR, S	
ART UNIT	**PAPER NUMBER**
1642	20

DATE MAILED: 02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/848,439	LaVallie et al
Examiner	**Group Art Unit**
Ungar	1642

☒ Responsive to communication(s) filed on *Nov 25, 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-17* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Upon review and reconsideration, the Suspension imposed on July 20, 1999 is withdrawn.

2. The Amendment filed February 26, 1999 (Paper No. 16) in response to the Office Action of November 25, 1998 is acknowledged and has been entered. The Examiner's Amendment of July 13, 1999 (Paper No. 18) has been entered. Previously pending claims 18-26 have been canceled and claims 1, 2, 7 and 11 have been canceled. Claims 1-17 are currently being examined.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 101

4. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

5. Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility, a well established utility or a substantial utility.

The disclosed utilities for the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2 include induction of expression of factors in and/or differentiation of tissue and organs, particularly inducing formation, growth, differentiation, proliferation and/or maintenance of

chondrocytes and/or cartilage tissue (p. 1, lines 5-15) and for treatment of cartilage disorders and/or maintenance of other tissue and organs including pancreatic, liver, spleen, lung kidney and/or other tissue as well as augmentation of activity of other tissue regenerating and differentiation factors. In particular, the specification teaches that the protein encoded by SEQ ID NO:1 is useful for binding Wnt protein and thus regulating the interaction of Wnt genes to receptor proteins (p. 5, lines 25-26). However, neither the specification nor any art of record teaches what the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2, does, they do not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases. The asserted utilities for the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2, are not considered "specific" utilities, i.e. they are not specific to the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2. Additional utilities for the claimed DNA include use for probes for the detection of mRNA encoding other Frazzled protein (p. 8, lines 24-27) and production of polypeptides (p. 9, lines 1-5) which then may be used to generate antibodies (p. 10, lines 10-15). These asserted utilities apply to many unrelated polynucleotide molecules and are therefore not considered "specific" to the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2.

The asserted utility of the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2, is based on the assertion that the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3

and SEQ ID NO:2, encodes a sequence which has homology to the Wnt binding domain of the extracellular binding domains of the Frizzled/Frazzled family of proteins (p. 4, lines 5-15). The specification teaches that it is of particular interest that the human SDF-5 gene appears to encode a secreted factor which may be capable of binding the Wnt protein and thus may be capable of regulating the binding interaction of Wnt genes to receptor proteins (para bridging pages 10-11). However, it was well known in the art, at the time the invention was made, that there was not a single Wnt family protein. Finch et al (PNAS, 1997, 94:6770-6775, IDS item) specifically teach that the Wnt family of proteins consists of more than a dozen structurally related molecules and that the Wnt family of proteins are involved, as extracellular signaling molecules, in cellular proliferation, migration, differentiation and tissue morphogenesis. Specifically Wnt proteins have been demonstrated to have important roles in development of midbrain and cerebellum, kidney tubologenesis and limb bud development (p. 6770, col 1). Further, Wang et al (JBC, 1996, 271:4468-4476, IDS item) specifically teaches that the Frizzled family is a large family of putative transmembrane receptors, 19 of which have been identified. These receptors are likely to play multiple roles in vertebrate development and/or physiology. The expression of frizzled family members in many different tissues and during embryonic development suggests that they are involved in a wide variety of developmental and/or homeostatic processes. Although the specification speculates that the encoded protein of SEQ ID NO:1 may be capable of binding the Wnt protein and thus capable of regulating the binding interaction of Wnt gene products to receptor proteins, there is no teaching of which

of the more than a dozen Wnt proteins the encoded product of SEQ ID NO:1 would be capable of binding or which receptor binding interactions SDF-5 would be capable of regulating.

The asserted utility of the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2 is further based on the homology of human SDF-5 to murine SDF-5, a protein that has the Wnt binding consensus sequence. Human SDF-5 was cloned using a nucleotide sequence of murine SDF-5 (p. 40). However, Finch et al, *Supra*, specifically teach that at the time the invention was made, little was known about the activity of murine SDF-5 (p. 6774, col 2). In addition, Shirozu et al (Genomics, 1996, 37:273-280) teach that although murine SDF5 shows some homology to the extracellular domains of a frizzled gene, its C-terminus has no homology with frizzled. Further Shirozu et al teach that SDF5 mRNA was expressed in brain, heart, kidney, lung and thymus but not in liver and spleen. A review of the specification revealed that the putative human homologue of murine SDF5, although expressed in mammary gland was not expressed in brain, lung, heart kidney. It is clear that the expression pattern of the mouse and human homologues are different. Importantly, Bork (Genome Research, 2000,10:398-400) clearly teaches that protein function is context dependent and that in determining protein function, both molecular and cellular aspects have to be considered (p. 398, col 2). Thus, even if human SDF-5 is an SDF-5-like protein or a Frizzled/Frazzled related protein, given the information in the specification and the art, it cannot be predicted what the isolated DNA molecule comprising DNA SEQ ID NO:1, encoding SEQ ID NO:3 and SEQ ID NO:2 is or what it does. There is no teaching

of a relationship to any specific disease or any involvement of the polynucleotide or encoded protein in the etiology of any specific disease. In order to determine a "real world use" for the claimed polynucleotide, additional experimentation is required, thus the invention does not have substantial utility. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids. Because the claimed invention is not supported by a specific asserted utility or by a substantial utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

7. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by a well established utility for the reasons set forth in the rejection under 35 USC 101 above, one skilled in the art clearly would not know how to use the claimed invention.

8. All other objections and rejections recited in Paper No. 15 are withdrawn.

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
February 11, 2000